

## CLAIMS

What is claimed is:

1. 1. A heat exchange/intra-aortic counterpulsation catheter device comprising:  
2 an elongate catheter having a proximal end and a distal end, said catheter being  
3 advancable, distal-end-first, into the aorta of a human or veterinary patient;  
4 a counterpulsation balloon useable for effecting intra-aortic balloon  
5 counterpulsation; and,  
6 a heat exchanger useable to cool at least a portion of the patient's body to a  
7 temperature that is at least 1 °C below normothermia.

1. 2. A device according to Claim 1 wherein the heat exchanger comprises a heat  
2 exchanger through which heat exchange fluid is circulated.

1. 3. A device according to Claim 2 wherein said heat exchanger comprises a heat  
2 exchange balloon.

1. 4. A device according to Claim 3 wherein the heat exchanger comprises a single-  
2 lobed heat exchange balloon.

1. 5. A device according to Claim 3 wherein the heat exchanger comprises a multi-lobed  
2 heat exchange balloon.

1. 6. A device according to Claim 1 wherein at least a portion of the heat exchanger is  
2 metallic.

1       7. A device according to Claim 3 wherein the heat exchange balloon and the  
2 counterpulsation balloon comprise a single balloon that is useable for both  
3 counterpulsation and heat exchange.

1       8. A device according to Claim 1 wherein the heat exchanger comprises a heat  
2 exchange surface and wherein the device further comprises a flow disruption surface  
3 associated with the heat exchange surface, the flow disruption surface being configured  
4 to disrupt the laminarity of blood flow adjacent to the heat exchange surface, thereby  
5 enhancing the efficiency by which the heat exchanger exchanges heat with the flowing  
6 blood.

1       9. A device according to Claim 1 wherein the counterpulsation balloon is positioned  
2 at a first location on the catheter and the heat exchanger comprises a heat exchange  
3 surface located at a second location on the catheter.

1       10. A device according to Claim 9 wherein the fist location is closer to the distal end of  
2 the catheter than the second location.

1       11. A device according to Claim 9 wherein the second location is closer to the distal  
2 end of the catheter than the first location.

1       12. A device according to Claim 9 wherein the heat exchanger and the counterpulsation  
2 balloon comprise a single balloon which is a) configured and useable to effect intra-aortic  
3 counterpulsation and b) receives a heat exchange medium such that heat is exchanged  
4 between the heat exchange medium and the blood, through at least a portion of the  
5 balloon.

1       13. A system comprising a heat exchange/intra-aortic counterpulsation catheter device  
2 according to Claim 1, further in combination with:

3                   apparatus attachable to the catheter and useable to cause a) inflation and deflation  
4 of the counterpulsation balloon in response to the patient's cardiac cycle to effect intra-  
5 aortic balloon counterpulsation that results in a beneficial effect on the patient and b) at  
6 least cooling (and preferable cooling or heating) of the heat exchanger to cause cooling of  
7 at least a portion of the patient's body (e.g., the heart) to a temperature that is at least 1  
8 °C below normothermia.

1       14. A method for treating a human or veterinary patient who suffers from congestive  
2 heart failure or another condition wherein the patient's cardiac output is subnormal, said  
3 method comprising the steps of:

- 4                   a. providing a heat exchange/intra-aortic counterpulsation catheter comprising  
5                   i) an elongate catheter having a proximal end and a distal end, said catheter  
6                   being advancable, distal-end-first, into the aorta of the patient, ii) a  
7                   counterpulsation balloon useable for effecting intra-aortic balloon  
8                   counterpulsation; and, a heat exchanger useable to cool at least a portion of  
9                   the patient's body to a temperature that is at least 1 °C below normothermia.
- 10               b. advancing the heat exchange/intra-aortic counterpulsation catheter, distal  
11               end first, into the patient's aorta such that the counterpulsation balloon is  
12               positioned in the thoracic aorta;
- 13               c. driving and controlling the counterpulsation balloon and heat exchanger so  
14               as to effect intra-aortic balloon counterpulsation while cooling and/or  
15               maintaining the temperature of at least a portion of the patient's body to a  
16               temperature that is at least 1 °C below normothermia.

1       15. A method according to Claim 14 further comprising the step of:

- 2               d. administering an antishivering treatment to the patient.

1 16. A method according to Claim 14, wherein the patient's body temperature is cooled  
2 to and maintained within the range of 32-34°C while intra-aortic counterpulsation is  
3 performed.

1 17. A method according to Claim 15 wherein the anti-shivering treatment is selected  
2 from the group of anti-shivering treatments consisting of: i) administering a therapeutically  
3 effective amount of an anti-shivering agent to the donor; ii) applying warmth to the skin of  
4 the donor and iii) administering a therapeutically effective amount of an anti-shivering agent  
5 to the donor and applying warmth to the skin of the donor.

1 18. A method according to Claim 15 wherein the anti-shivering treatment comprises  
2 administering to the donor a therapeutically effective amount of at least one anti-shivering  
3 agent selected from the group consisting of: i) dopamine receptor antagonists; ii) dopamine  
4 receptor agonists; iii) κ-opioid receptor agonists; iv) opioid agonist-antagonist analgesics;  
5 v) serotonin 5HT1a receptor agonists and vi) alpha-2 adrenergic receptor agonists.

1 19. A method for treating a human or veterinary patient who suffers from congestive  
2 heart failure or another condition wherein the patient's cardiac output is subnormal, said  
3 method comprising the steps of:

- 4 a. providing a heat exchange catheter comprising i) a heat exchange catheter  
5 body and ii) at least one heat exchanger for exchanging heat with blood  
6 flowing through a blood vessel into which the heat exchange catheter body  
7 is inserted;
- 8 b. providing an intra-aortic balloon counterpulsation catheter comprising i) a  
9 counterpulsation catheter body and ii) a counterpulsation balloon useable  
10 for effecting intra-aortic balloon counterpulsation;
- 11 c. inserting the heat exchange catheter into the patient's vasculature such that  
12 blood flows in heat exchange proximity to the heat exchanger;

13       d. inserting the intra-aortic balloon counterpulsation catheter into the patient's  
14       vasculature such that the counterpulsation balloon is positioned within the  
15       patient's aorta;  
16       e. using the intra-aortic balloon counterpulsation catheter to effect intra-aortic  
17       balloon counterpulsation; and,  
18       f. using the heat exchange catheter to cool the temperature of at least a  
19       portion of the patient's body to a temperature that is at least 1 °C below  
20       normothermia.

1       20. A method according to Claim 19 further comprising the step of:  
2       g. administering an antishivering treatment to the patient.

1       21. A method according to Claim 20 wherein the anti-shivering treatment  
2       is selected from the group of anti-shivering treatments consisting of: i) administering a  
3       therapeutically effective amount of an anti-shivering agent to the donor; ii) applying warmth  
4       to the skin of the donor and iii) administering a therapeutically effective amount of an anti-  
5       shivering agent to the donor and applying warmth to the skin of the donor.

1       22. A method according to Claim 20 wherein the anti-shivering treatment comprises  
2       administering to the donor a therapeutically effective amount of at least one anti-shivering  
3       agent selected from the group consisting of: i) dopamine receptor antagonists; ii) dopamine  
4       receptor agonists; iii) κ-opioid receptor agonists; iv) opioid agonist-antagonist analgesics,  
5       v) serotonin 5HT1a receptor agonists and vi) alpha-2 adrenergic receptor agonists.

1       23. A method according to Claim 19, wherein the patient's body temperature is cooled  
2       to and maintained within the range of 32-34°C while intra-aortic counterpulsation is  
3       performed.

1       24. A method according to Claim 19 wherein the heat exchanger is positioned in a vein.

1 25. A method according to Claim 24 wherein the heat exchanger is positioned in the  
2 vena cava.